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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,392	12/12/2001	Kevin P. Baker	P2830P1C58	9874

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,392	GENENTECH, INC.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35,38-40 and 44-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33-35 and 38-40* is/are allowed.

6)☒ Claim(s) *28-32 and 44-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 9/15/04 has been entered into the record.

B. Claims 28-35, 38-40 and 44-47 were pending in the Applicants. New claims 48-59 were added. Therefore, claims 28-35, 38-40 and 44-59 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Declaration under 37 CFR 1.132

A. Applicants have submitted a Declaration under 37 CFR 1.132 by Dr. Ashkenazi on 9/15/04 regarding the use of gene amplification data as a demonstration of utility. It appears, however, that this Declaration belongs in Application No. 09/903,925. This Declaration would be persuasive in establishing utility of the polynucleotides of the present invention. Furthermore, the chondrocyte proliferation assay is sufficient to establish utility of the proteins of the present invention.

3. Priority

A. Applicant asserts that PCT/US00/04342, filed February 18, 2000 discloses a MLR (mixed lymphocyte reaction; Assay #137) assay and that the data generated in the MLR assay establish patentable utility. However, a review of the instant application and this assay do not lead to a conclusion of utility based on this assay, and therefore, priority to this PCT is not afforded for the reasons of record. Based on the MLR assay, the effective filing date of the instant application is still based on present application, filed 12/12/01 for the reasons of record.

Applicants further assert that the present invention possess utility based on gene amplification data. This is deemed persuasive. Finally, Applicants argue that the present invention possesses utility based on the chondrocyte proliferation assay. This is deemed persuasive. **Therefore, the present invention deserves priority to 60/162,506, filed October 29, 1999, the date of the gene amplification disclosure.**

4. Information Disclosure Statement

A. The Information Disclosure Statement dated 9/15/04 has been entered into the record. All references have been considered.

5. Specification

A. All objections to the specification have been withdrawn in view of Applicants' amendments.

6. Claim Objections

A. The objection to claims 28-35, 38-40 and 44-47 has been withdrawn in view of Applicants' amendments to the claims.

B. Claims 28-35, 38 and 39 are objected to since the parentheses should be removed from "(SEQ ID NO:270)" and "(SEQ ID NO:271)."

7. Claim Rejections - 35 USC § 101

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 101 has been withdrawn in view of the fact that the polynucleotides of the present invention have utility in gene therapy and the chondrocyte proliferation assay.

For completion of the record, the following will be addressed. Applicants rely on a Declaration under 37 CFR 1.132 by Dr. Fong. Considering Applicants' arguments in the absence of the Declaration, the assertion that a protein showing 80% inhibition compared to control is an immunosuppressor is an assertion not supported by any facts or evidence of record. First, the instant specification fails to disclose the degree of activity for the claimed invention in the MLR assay. The specification states that any decrease compared to control is considered positive for immunosuppression. Therefore, there is no disclosure that the activity in the assay was at least 80%, only that this value is preferred. Therefore, the Declaration, itself, is not be persuasive to overcome the holding of a lack of utility for the claimed invention based on the MLR assay.

8. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that the proteins of the present invention have utility in gene amplification and the chondrocyte proliferation assay. Therefore, the claims are enabled.

B. Claims 28-35, 38-40 and 44-47 remain rejected under 35 USC 112, first paragraph. The Budapest Treaty states that the cell line will be maintained for 30 years, or 5 years from date of last request. Reference to "5 years" has not been disclosed in the specification.

C. Claims 28-32 and 44-47 remain rejected and new claims 48-59 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of the Office Action mailed 3/15/04.

Applicants have removed reference to the "extracellular domain." Therefore, this part of the rejection is obviated. Applicants argue that the claims have been amended to include a functional recitation and, based on this, the artisan would not require undue experimentation to make and use the claimed invention.

These arguments have been considered, but are not deemed persuasive. Claims 28-32 are not enabled since the specification does not provide any guidance or working examples of proteins which are immunosuppressors, nor does it teach how to make such a protein even if, arguendo, the full length of PRO1410 were an immunosuppressant.

Regarding claims 48-59, the Examiner does not question that the chondrocyte proliferation assay is well-described in the specification or that the full-length polynucleotides are amplified in tumors. All of these claims, including claims 28-32 are not enabled since the claims are broad because they do not require the claimed polynuclotide to be identical to the disclosed sequence and because the claims have no functional limitation." While Applicants have amended the claims to recite a functional limitation, the issue remains that the claims are broad because they do not require the claimed polynucleotide be identical to the disclosed sequence. Applicants have only enabled the use of the full-length polynucleotide of SEQ ID NO:270 in gene amplification and the encoded protein of SEQ ID NO:271 (and that encoded by ATCC No. 203277) to induce chondrocyte proliferation. However, Applicants have provided no functional limitation for the "hybridization" claims. Nowhere in the specification do Applicants disclose working examples of polypeptides which are less than the full-length of SEQ ID NO:271. Polypeptides which are less than the full-length of SEQ ID NO:271 would have one or more amino acid substitutions, deletions, insertions and/or additions to the polypeptide of SEQ ID NO:271. Applicants have not provided any guidance as to what critical residues are required to maintain the functional characteristics (i.e. chondrocyte proliferation, or, for that matter, immunosuppression) of the polypeptide of SEQ ID NO:271, nor is it predictable to one of ordinary skill in the art how to make a functional polypeptide which is less than 100% identical to that of SEQ ID NO:271. Furthermore, Applicants have not demonstrated that any polynucleotide other than that of SEQ ID NO:270 is amplified in the tumors described in the specification, or what the function would be of those polynucleotides which hybridize to those of the present invention.

In summary, the breadth of the claims remains excessive with regard to Applicants claiming all polypeptides which are less than the full-length of SEQ ID NO:271 as well as their encoding

polynucleotides. There is also a lack of guidance and working examples of these polypeptides and polynucleotides as well as which residues are critical for polypeptide function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional polypeptide other that that of SEQ ID NO:271, or which polynucleotides other than that of the full-length of SEQ ID NO:270 would be amplified in tumors, leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

D. No rejection is being made over claim 46 even though it does not recite that the host cell is "isolated." When read in light of the specification, these claims do not read on gene therapy. As defined in the specification "host cells are transfected or transformed with expression or cloning vectors described herein for PRO production *and cultured in conventional nutrient media* modified as appropriate for inducing promoters, selecting transformants, or amplifying the genes encoding the desired sequences" (emphasis added). The fact that these cells are cultured in conventional media demonstrates that these host cells are not transgenic. If Applicants disagree, they should amend the claim to recite that the host cell is "isolated."

9. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to include a functional limitation.

10. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 28-35, 38-45 and 44-47 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claims to remove recitation of "extracellular domain."

B. The rejection of claims 41-43 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' cancellation of the claims and the fact that new claim 53-59 recite hybridization conditions.

11. Claim Rejections - 35 USC § 102

A. The rejection of claims 28-35, 38-40 and 44-47 under 35 USC 102 as being anticipated by Ashkenazi has been withdrawn in view of the fact that the present invention receives priority prior to the filing date of Ashkenazi.

12. Conclusion

A. Claims 33-35 and 38-40 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 15, 2004

ROBERT LANDSMAN
PATENT EXAMINER